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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/994,923	11/28/2001	William R. Law	21726/92990	7447

23644 7590 06/21/2002

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EXAMINER

CRANE, LAWRENCE E

ART UNIT PAPER NUMBER

1623

DATE MAILED: 06/21/2002

7

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No. <b>09/994,923</b>	Applicant(s) <b>W. R. Law</b>	
	Examiner <b>L. E. Crane</b>	Group Art Unit <b>1623</b>	

**- THE MAILING DATE of this communication appears on the cover sheet beneath the correspondence address -**

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE **--3--** MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be filed after six months from the date of this communication.
- If the prior for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 USC §133).

## Status

- ☒ Responsive to communication(s) filed on **-01/30/02 (Drawings) and 01/31/02 (amdt A)-**.
- ☐ This action is **FINAL**.
- ☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

## Disposition of Claims

- ☒ Claims **--1-16--** are pending in the application. Claims **-[]-** have been cancelled.
- Of the above claim(s) **--[]-** is/are withdrawn from consideration.
- ☐ Claim(s) **--[]-** is/are allowed.
- ☒ Claims **--1-16--** are rejected.
- ☐ Claim(s) **--[]-** is/are objected to.
- ☐ Claim(s) **--[]-** are subject to restriction or election requirement.

## Application Papers

- ☒ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The proposed drawing correction, filed on **-[]-** are ☐ approved ☐ disapproved.
- ☒ The drawing(s) filed on **-01/30/02-** are objected to by the Examiner.
- ☐ The specification is objected to by the Examiner.
- ☒ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119(a)-(d)

- ☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119 (a)-(d).
- ☐ All ☐ Some ☒ None of the CERTIFIED copies of the priority documents have been received.
- ☐ received in Application No. (Series Code/Serial Number) **-[]-**.
- ☐ received in the national stage application from the International Bureau (PCT Rule 17.2(a)).
- \* Certified copies not received: **-[]-**.

## Attachment(s)

- ☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). **--[]--**
- ☒ Notice of Reference(s) Cited, PTO-892
- ☒ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Interview Summary, PTO-413
- ☐ Notice of Informal Patent Application, PTO-152
- ☐ Other: **-[]-**

U.S. Patent Trademark Office

## Office Action Summary

PTO-326 (Rev. 06/19/01)  
S. N. 09/994,923

Part of Paper No. **07**

Copy for ☒ **FILE** ☐ **APPLICANT**

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The oath or declaration is defective. A new oath or declaration in compliance with 37 C.F.R. §1.67(a) identifying this application by its Serial Number and filing date is required. See MPEP 602.01 and 602.02. The oath or declaration is defective because:

5 It does not identify and claim the U.S. priority relationship indicated in applicant's preliminary amendment filed January 31, 2002. Also, it is unclear whether the instant case is a filing under 35 U.S.C. §371 or not. Clarification of the filing status is respectfully requested along with any necessary amendments to the substitute declaration and to the first  
10 paragraph of page one (1) of the disclosure required by said clarification.

No claims have been cancelled, added or amended and the disclosure has been amended as per the preliminary amendment filed January 31, 2002. No Information Disclosure Statement (IDS) has been  
15 received as of the date of the instant Office action.

Claims 1-16 remain in the case.

The disclosure is objected to because of the following informalities:

The drawings received January 30, 2002 have been reviewed by the draftsperson and by instant Examiner. The chemical structures  
20 presented in individual figures may be incorporated into the specification as well (see the '084 and '432 patent documents as examples). However, the chemical structure in Figure 12 defined in the disclosure as representing "ARADS" includes a variable "R" which has not been defined, thereby rendering the disclosure incomplete.

25 Appropriate correction is required.

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35 U.S.C. §101 reads as follows:

"Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title."

5        Claims 15 and 16 are rejected under 35 U.S.C. §101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. §101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd. App., 1967) and *Clinical*  
10    *Products, Ltd. v. Brenner*, 255 F. Supp. 131, 149, 149 USPQ 475 (D.D.C. 1966).

      Claims 5-6 and 15 are rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the  
15    invention.

      In claims 5 and 6 the terms "EHNA" and "ARADS" are indefinite for failure to provide a complete chemical name or names; e.g. -- ethanol (EtOH) --. Applicant is referred to the objection supra concerning the acronym "ARADS" as found in Figure 12.

20        Claim 15 was possibly styled as a pharmaceutical composition claim, but if this was applicant intent, the resultant claim is incomplete because only one ingredient has been specified. The standard format for this kind of claim is as follows: -- A pharmaceutical composition comprising {active ingredient(s)} in combination with a  
25    pharmaceutically acceptable carrier.--

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The non-statutory double patenting rejection, whether of the obviousness-type or non-obviousness-type, is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent. *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); *In re Van Ornam*, 686 F. 2d 937, 214 USPQ 761 (CCPA 1982); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir 1985); and *In re Goodman*, 29 USPQ 2d 2010 (Fed. Cir. 1993).

A timely filed terminal disclaimer in compliance with 37 C.F.R. § 1.321(b) and (c) may be used to overcome an actual or provisional rejection based on a non-statutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 C.F.R. §1.78(d).

Effective January 1, 1994, a registered attorney or agent or record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 C.F.R. §3.73(b).

Claims 1-14 and 16 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-11 of U.S. Patent No. 6,103,702. Although the conflicting claims are not identical, they are not patentably distinct from each other because the method of treatment and the alleged active ingredients are directed to substantially overlapping subject matter. See the definition of "Sepsis" in the portion of "Taber's Cyclopedic Medical Dictionary (PTO-892 ref. S) and note that the instant claims refer to examples of the symptoms of sepsis.

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The following is a quotation of the appropriate paragraphs of 35 U.S.C. §102 that form the basis for the rejections under this section made in this Office action:

"A person shall be entitled to a patent unless -

5 (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent."

10 (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States."

Claim 15 is rejected under 35 U.S.C. §102(b) as being anticipated by Ryder et al. '785 (PTO-892 ref. E).

15 Applicant is referred to the '785 patent at columns 13-15 wherein several "PHARMACEUTICAL COMPOSITIONS" of pentostatin are specifically disclosed.

20 Assuming that the noted claim was intended to be directed solely to pharmaceutical compositions of ADA inhibitors known in the art, the same grounds applied above are also deemed to apply to EHNA and ARADS all of which are also anticipated in light of applicant's own admissions in the disclosure.

25 Papers related to this application may be submitted to Group 1600 via facsimile transmission(FAX). The transmission of such papers must conform with the notice published in the Official Gazette (1096 OG 30, November 15, 1989). The telephone numbers for the FAX machines operated by Group 1600 are (703) 308-4556 and 703-305-3592.

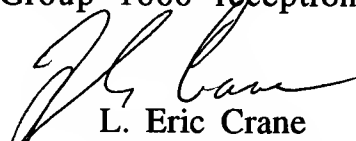
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5 Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner L. E. Crane whose telephone number is 703-308-4639. The examiner can normally be reached between 9:30 AM and 5:00 PM, Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. Johann R. Richter, can be reached at (703)-308-4532.

10 Any inquiry of a general nature or relating to the status of this application should be directed to the Group 1600 receptionist whose telephone number is 703-308-1235.

LECrane:lec  
06/20/02

  
L. Eric Crane  
Patent Examiner  
Group 1600